SLOVENSKI STANDARD
SIST EN IEC 63045:2020

01-november-2020

Ultrazvok - Viri nefokusiranih kratkih impulzov tlaka, vključno z viri balističnih impulzov tlaka - Karakteristike polj (IEC 63045:2020)

Ultrasonics - Non-focusing short pressure pulse sources including ballistic pressure pulse sources - Characteristics of fields (IEC 63045:2020)

Ultraschall - Quellen für nicht fokussierte kurze Druckimpulse einschließlich pneumatischen und ballistischen Druckpulsquellen - Feldcharakterisierung (IEC 63045:2020)

Ultrasons - Sources d'impulsions de pression courtes sans focalisation, y compris les sources d'impulsions de pression balistiques - Caractéristiques des champs (IEC 63045:2020)

Ta slovenski standard je istoveten z: **EN IEC 63045:2020**

ICS:

11.040.60	Terapevtska oprema	Therapy equipment

SIST EN IEC 63045:2020 **en**

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN IEC 63045

July 2020

ICS 17.140.50

English Version

Ultrasonics - Non-focusing short pressure pulse sources including ballistic pressure pulse sources - Characteristics of fields (IEC 63045:2020)

Ultrasons - Sources d'impulsions de pression courtes sans focalisation, y compris les sources d'impulsions de pression balistiques - Caractéristiques des champs (IEC 63045:2020)

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European Committee for Electrotechnical Standardization
Comité Européen de Normalisation Electrotechnique
Europäisches Komitee für Elektrotechnische Normung

CEN-CENELEC Management Centre: Rue de la Science 23, B-1040 Brussels

European foreword

The text of document 87/741/FDIS, future edition 1 of IEC 63045, prepared by IEC/TC 87 "Ultrasonics" was submitted to the IEC-CENELEC parallel vote and approved by CENELEC as EN IEC 63045:2020.

The following dates are fixed:

- latest date by which the document has to be implemented at national level by publication of an identical national standard or by endorsement (dop) 2021-03-29
- latest date by which the national standards conflicting with the document have to be withdrawn (dow) 2023-06-29

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CENELEC shall not be held responsible for identifying any or all such patent rights.

Endorsement notice

The text of the International Standard IEC 63045:2020 was approved by CENELEC as a European Standard without any modification.

In the official version, for Bibliography, the following notes have to be added for the standards indicated:

IEC 60601-2-62	NOTE	Harmonized as EN 60601-2-62
IEC 60601-2-36	NOTE	Harmonized as EN 60601-2-36
IEC 61689	NOTE	Harmonized as EN 61689
IEC 61828:2001	NOTE	Harmonized as EN 61828:2001 (not modified)
IEC 63009	NOTE	Harmonized as EN IEC 63009

Annex ZA
(normative)

Normative references to international publications with their corresponding European publications

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

NOTE 1 Where an International Publication has been modified by common modifications, indicated by (mod), the relevant EN/HD applies.

NOTE 2 Up-to-date information on the latest versions of the European Standards listed in this annex is available here: www.cenelec.eu.

Publication	Year	Title	EN/HD	Year
IEC 60565-1	-	Underwater acoustics - Hydrophones - Calibration of hydrophones - Part 1: Procedures for free-field calibration of hydrophones	EN IEC 60565-1	-
IEC 60565-2	-	Underwater acoustics - Hydrophones - Calibration of hydrophones - Part 2: Procedures for low frequency pressure calibration	EN IEC 60565-2	-
IEC 62127-1	2007	Ultrasonics - Hydrophones - Part 1: Measurement and characterization of medical ultrasonic fields up to 40 MHz	EN 62127-1	2007
IEC 62127-2	2007	Ultrasonics - Hydrophones - Part 2: Calibration for ultrasonic fields up to 40 MHz	EN 62127-2	2007
IEC 62127-3	-	Ultrasonics - Hydrophones - Part 3: Properties of hydrophones for ultrasonic fields up to 40 MHz	EN 62127-3	-

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INTERNATIONAL STANDARD

Ultrasonics – Non-focusing short pressure pulse sources including ballistic pressure pulse sources – Characteristics of fields

INTERNATIONAL
ELECTROTECHNICAL
COMMISSION

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INTERNATIONAL ELECTROTECHNICAL COMMISSION

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ULTRASONICS – NON-FOCUSING SHORT PRESSURE PULSE SOURCES INCLUDING BALLISTIC PRESSURE PULSE SOURCES – CHARACTERISTICS OF FIELDS

FOREWORD

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International Standard IEC 63045 has been prepared by IEC technical committee 87: Ultrasonics.

The text of this International Standard is based on the following documents:

FDIS	Report on voting
87/741/FDIS	87/743/RVD

Full information on the voting for the approval of this International Standard can be found in the report on voting indicated in the above table.

This document has been drafted in accordance with the ISO/IEC Directives, Part 2.

Words in **bold** in the text are defined in Clause 3.

The committee has decided that the contents of this document will remain unchanged until the stability date indicated on the IEC website under "http://webstore.iec.ch" in the data related to the specific document. At this date, the document will be

- reconfirmed,
- withdrawn,
- replaced by a revised edition, or
- amended.

IMPORTANT – The 'colour inside' logo on the cover page of this publication indicates that it contains colours which are considered to be useful for the correct understanding of its contents. Users should therefore print this document using a colour printer.

INTRODUCTION

In this document, **pressure pulses** are single pulses of ultrasonic energy of up to 25 μs duration which have only one significant positive and one negative peak carrying more than 95 % of the energy (see definitions). Focused **pressure pulses** (sometimes called "strongly focused") are characterized by a peak acoustic pressure in a point in the sound field distant from the **source aperture**. Parameters and measurement methods for focusing **pressure pulse** sources are described in IEC 61846. The parameters and measurement methods of any other types of **pressure pulses**, i.e. weakly focused and non-focused **pressure pulses**, are described in this document.

Devices with non-focusing/weakly focusing **pressure pulse** sources are used for the extracorporeal treatment of soft tissue pain situations in, for example, the shoulder, the heel spur or the tennis elbow and for trigger point therapy. Further, still under research are applications in orthopaedics, pain therapy, treatment of angina pectoris, stem cell therapy of infarcted cardiac areas, treatment of erectile dysfunction, of cellulitis, and wound repair.

The patients receive between 3 to 5 treatments of 10 min to 20 min duration with approximately or on average 1 000 pulses. Each **pressure pulse** consists of one significant compressional part and a trailing negative part and has an overall duration of less than 25 μs. In present devices, 1 to 35 pulses per second are released to the target tissue. The pulses are usually applied to the patient by a manually guided hand piece. Targeting is commonly done by asking the patient to direct the pulses to the point of maximum pain.

The first use of non-focused/weakly focused **pressure pulses** to treat soft tissue pain situations was described in 1999. The first devices used the ballistic principle for the generation of the **pressure pulses**, which is based on an "air-gun" like acceleration of a projectile by pressurized air. The projectile impinges on the rear side of a larger metal **applicator**, the front side of which instantly releases one fast **pressure pulse** to the patient. Today, most of the devices on the market use this design and often are called “radial shock wave devices” or “ballistic sources” although a true shock wave is not created. Also, other pulse generating principles are being applied including variations of common lithotripter sources (electromagnetic, piezoelectric, electrohydraulic).

Before this first occurrence, focused **pressure pulses** were used clinically beginning in 1993 for the treatment of shoulder calcifications, tennis elbow pain and heel spur pain, initially using lithotripter-like electrohydraulic, electromagnetic or piezoelectric sources. These focused **pressure pulses** can be characterized by IEC 61846, but the parameters described therein are not sufficiently applicable to characterize the parameters and fields of weakly focused and non-focused **pressure pulses** and their propagation characteristics.

This document specifies methods of measuring and characterizing the acoustic **pressure pulses** generated by non-focusing/weakly focusing **pressure pulse equipment** and their propagation characteristics.

ULTRASONICS – NON-FOCUSING SHORT PRESSURE PULSE SOURCES INCLUDING BALLISTIC PRESSURE PULSE SOURCES – CHARACTERISTICS OF FIELDS

1 Scope

This document is applicable to

– therapy equipment using extracorporeally induced non-focused or weakly focused **pressure pulses**;

– therapy equipment producing extracorporeally induced non-focused or weakly focused mechanical energy,

where the **pressure pulses** are released as single events of duration up to 25 μs.

This document does not apply to

– therapy equipment using focusing **pressure pulse** sources such as extracorporeal lithotripsy equipment;

– therapy equipment using other acoustic waveforms like physiotherapy equipment, low intensity ultrasound equipment and HIFU/HITU equipment.

This document specifies

– measurable parameters which are used in the declaration of the acoustic output of extracorporeal equipment producing a **non-focused** or **weakly focused pressure pulse field**,

– methods of measurement and characterization of **non-focused** or **weakly focused pressure pulse fields**.

NOTE 1 The parameters defined in this document do not – at the time of publication – allow quantitative statements to be made about clinical efficacy and possible hazard. In particular, it is not possible to make a statement about the limits for these effects.

NOTE 2 Figure B.1 to Figure B.10 and Figure 2 to Figure 4 are useful to understand the geometry of the field applied in this document.

This document has been developed for equipment intended for use in **pressure pulse** therapy, for example therapy of orthopaedic pain like shoulder pain, tennis elbow pain, heel spur pain, muscular trigger point therapy, lower back pain, etc. It is not intended to be used for extracorporeal lithotripsy equipment (as described in IEC 61846), physiotherapy equipment using other waveforms (as described in IEC 61689) and HIFU/HITU equipment (see IEC 60601-2-62 and IEC TR 62649).

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

IEC 60565-1, *Underwater acoustics – Hydrophones – Calibration of hydrophones – Part 1: Procedures for free-field calibration of hydrophones*

IEC 60565-2, *Underwater acoustics – Hydrophones – Calibration of hydrophones – Part 2: Procedures for low frequency pressure calibration*

IEC 62127-1:2007, *Ultrasonics – Hydrophones – Part 1: Measurement and characterization of medical ultrasonic fields up to 40 MHz*
IEC 62127-1:2007/AMD1:2013

IEC 62127-2:2007, *Ultrasonics – Hydrophones – Part 2: Calibration for ultrasonic fields up to 40 MHz*

IEC 62127-3, *Ultrasonics – Hydrophones – Part 3: Properties of hydrophones for ultrasonic fields up to 40 MHz*

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

- IEC Electropedia: available at http://www.electropedia.org/
- ISO Online browsing platform: available at http://www.iso.org/obp

3.1
applicator
part of the ballistic **pressure pulse** source which emits the **pressure pulses** to the patient

Note 1 to entry: In the case of a ballistic **pressure pulse** source, the front side of the **applicator** is often coupled to the skin of the patient using an ultrasound coupling gel or other agent and releasing the **pressure pulses** to the patient. In this case, the front of the **applicator** is equal to the **source aperture**.

Note 2 to entry: Depending on the design of the source, there may be a space between the source emitting the **pressure pulses** (e.g. membrane, surface of piezoelectric crystals, spark gap etc.) and the **source aperture**. Usually, this space is composed of an acoustically conducting pad coupling material or a fluid, which transmits the **pressure pulses** from the source to the **source aperture** (see 3.48).

3.2
beam $-n$ dB cross-sectional area
$A_{z,n\mathrm{dB}}$
area enclosed by the **peak-positive acoustic pressure** contour in any plane perpendicular to the **beam axis**, where all points on the contour have a pressure of $-n$ dB relative to the value at the **beam axis** in this plane

Note 1 to entry: The value of n and the axial distance z from the measurement centre point shall be stated as subscript.

Note 2 to entry: Typical values of $-n$ dB are: −3 dB, −6 dB, −10 dB, −12 dB, −20 dB. Reasonable values of n for clinical approval and communication to the users can be identified by a risk analysis process, by applicable safety standards, by consulting notified bodies, expert communities (e.g. ISMST – International Society for Medical Shockwave Treatment) or through literature.

Note 3 to entry: The **beam $-n$ dB cross-sectional area** is expressed in units of metre squared (m^2).

3.3
beam $-n$ dB extent
$z_{\mathrm{b},n\mathrm{dB}}$
distance along the **beam axis** from the **source aperture** to the point where the **peak-positive acoustic pressure** has dropped farthest by $-n$ dB relative to the acoustic pressure at the **source aperture**

Note 1 to entry: The value of n shall be stated as subscript.

Note 2 to entry: Typical values of $-n$ dB are: −3 dB, −6 dB, −10 dB, −12 dB, −20 dB. Reasonable values of n for clinical approval and communication to the users can be identified by a risk analysis process, by applicable safety standards, by consulting notified bodies, expert communities (e.g. ISMST – International Society for Medical Shockwave Treatment) or through literature.

Note 3 to entry: The **beam $-n$ dB extent** is expressed in metres (m).